Attorney Docket No.: 5261.210-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Johannessen et al.

Application No.: To be assigned Group Art Unit: To be assigned

Filed: October 25, 2001 Examiner: To be assigned

For: Subcutaneous Factor VIIA

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

IN THE SPECIFICATION:

At page 1, line 4, please insert:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Serial No. 09/148,440 filed on September 4, 1998, and claims priority under 35 U.S.C. 119 of Danish application no. 1038/97 filed on September 10, 1997, and U.S. provisional application no. 60/059,236 filed on September 18, 1997, the contents of which are fully incorporated herein by reference.--

IN THE FIGURES:

Please delete the previous figures (Figure 1a-1d, and Figure 2a-2d), and replace with the attached Figures 1a-1d and 2a-2d.

IN THE CLAIMS:

Please cancel claims 1-31 without prejudice or disclaimer.

Add new claims 32-41 reading as follows:

--32. A method for treatment of a disease affectable by Factor VIIa (FVIIa), said method comprising administering subcutaneously to a mammal in need thereof an effective amount for treating said disease of a composition comprising modified FVIIa, wherein said modified FVIIa has substantially the same biological activity for blood coagulation as authentic FVIIa.--

--33. A method for prolonging the biological half-life of Factor VIIa (FVIIa) being administered to a mammal, said method comprising administering to a mammal in need thereof by subcutaneous injection a composition comprising modified FVIIa, wherein said modified FVIIa has substantially the same biological activity for blood coagulation as authentic FVIIa.--

--34. The method of claim 32 wherein the disease is haemophilia A or B.--

--35. The method of claim 32 wherein the Factor VIIa is recombinant human Factor VIIa.--

--36. The method of claim 32 wherein the composition is a stable aqueous solution ready for administration.--

--37. The method of claim 32 wherein the composition is dried and reconstituted with a pharmaceutically acceptable vehicle suitable for injection prior to administration.--

--38. The method of claim 33 wherein said mammal suffers from haemophilia A or B.--

--39. The method of claims 33 wherein the Factor VIIa is recombinant human Factor VIIa.--

--40. The method of claim 33 wherein the composition is a stable aqueous solution ready for administration.--

--41. The method of claim 33 wherein the composition is dried and reconstituted with a pharmaceutically acceptable vehicle suitable for injection prior to administration.--

REMARKS

Entry of this amendment is respectfully requested.

In this amendment, claims 1-31 are cancelled without prejudice and new claims 32-41 are presented. Support for the new claims can be found in the specification and original claims. For example, modified Factor VIIa having substantially the same biological activity for blood coagulation as authentic Factor VIIa is disclosed at page 7, lines 5-9. No new matter is added. Accordingly, claims 32-41 are pending and at issue.

The substitute figures represent formal drawings to replace the informal drawings originally filed. No new matter is added.

It is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: October 25, 2001

Reza Green, Reg. No. 38,475
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

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Individual Plasma Concentration Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

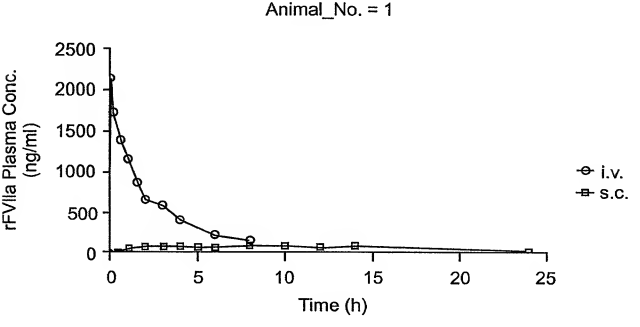

FIG 1A

Individual Plasma Concentration Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

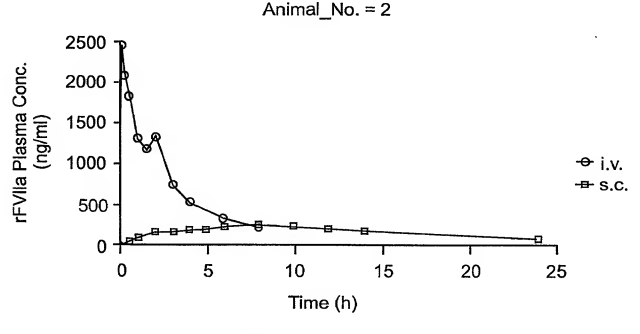

FIG 1B

Individual Plasma Concentration Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

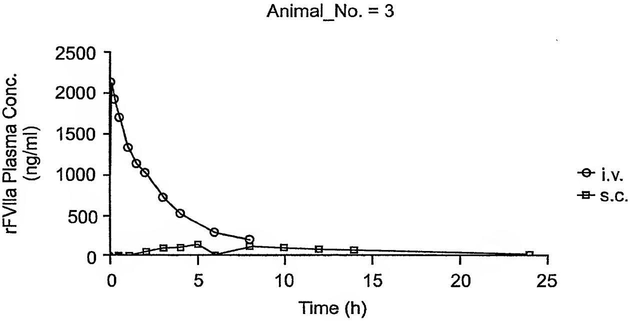

FIG 1C

Individual Plasma Concentration Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

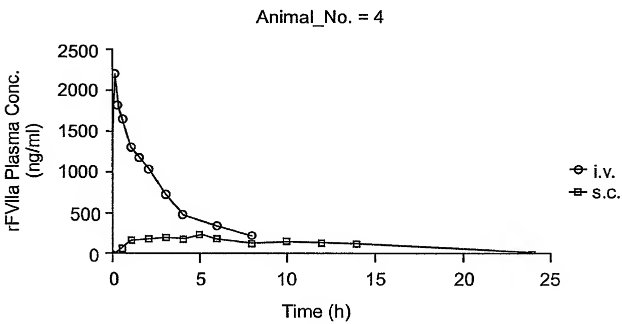

FIG 1D

Individual Plasma Activity Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

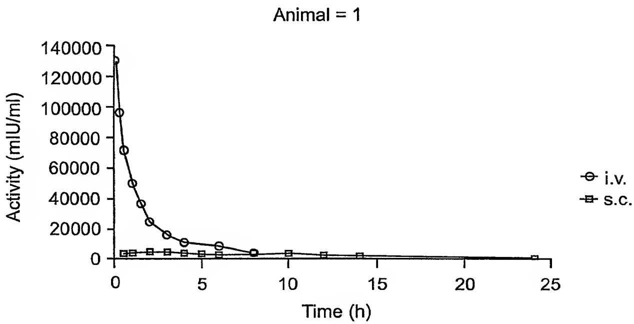

FIG 2A

Individual Plasma Activity Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

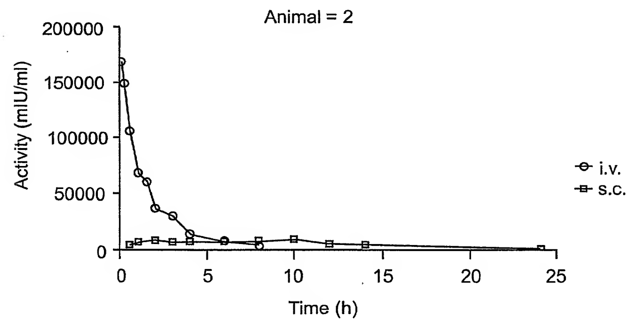

FIG 2B

Individual Plasma Activity Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

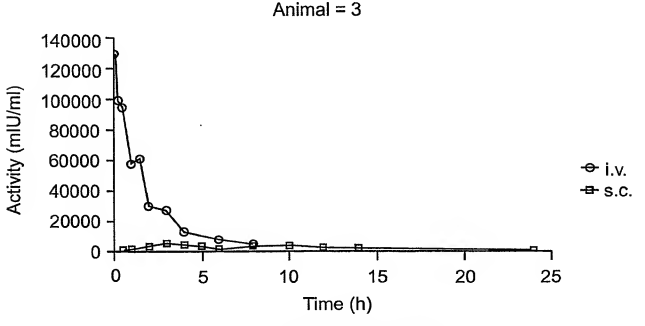

FIG 2C

Individual Plasma Activity Profiles of rFVIIa Following Intravenous (i.v.) and Subcutanous (s.c.) Administration of 0.2 mg/kg to Minipigs

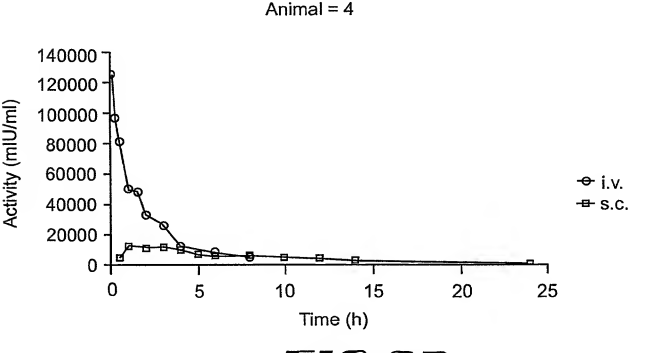

FIG 2D